



# U.S. Public Interest Research Group

## National Association of State PIRGs

December 6, 2005

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Division of Dockets Management  
 Food and Drug Administration  
 Department of Health and Human Services  
 5630 Fishers Lane, Room 1061  
 Rockville, MD 20852

### To Whom It May Concern:

This letter serves to amend the petition originally submitted, dated November 21, 2005, as requested by Lyle Jaffe of the FDA Division of Dockets Management on December 2, 2005.

### ACTION REQUESTED

The undersigned submits this petition under Section 601 of the Federal Food, Drug and Cosmetic Act to request the Food and Drug Administration (FDA) to use its authority to require manufacturers to stop using xylene, toluene, and dibutyl phthalate in nail polish marketed for children under the age of 14.

### STATEMENT OF GROUNDS

In the course of doing research for its 20<sup>th</sup> annual toy safety survey, the U.S. Public Interest Research Group<sup>1</sup> (U.S. PIRG) found several examples of play cosmetic sets marketed for children with nail polish containing toxic chemicals, such as toluene, xylene and dibutyl phthalate.<sup>2</sup> In some cases, the product packaging displayed Disney characters to attract the youngest consumers; other products containing these chemicals were found in stores such as Limited Too and Claire's, which target the so-called "tween" consumers under the age of 14. Please see the attached list of products containing toluene, xylene and dibutyl phthalate that we found on store shelves.

Play cosmetics—cosmetics intended for children under 14—must conform to the requirements of the Federal Food, Drug and Cosmetic Act (FD&C Act).<sup>3</sup> Under the FD&C Act, a cosmetic is deemed adulterated—and therefore subject

<sup>1</sup> U.S. Public Interest Research Group (U.S. PIRG) is the national advocacy office of the state PIRGs. The state PIRGs are a nationwide network of nonprofit, nonpartisan, state-based public interest advocacy organizations. The state PIRGs' mission is to deliver persistent, result-oriented activism that protects the environment, encourages a fair marketplace for consumers, and fosters responsive, democratic government.

<sup>2</sup> U.S. PIRG Education Fund, *Trouble in Toyland*, November 2005. Available at [www.toysafety.net](http://www.toysafety.net).

<sup>3</sup> ASTM F963, Section 4.3.4.

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to regulatory action—if it contains any “poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or, under such conditions of use as are customary or usual.”<sup>4</sup> We believe toluene, xylene and dibutyl phthalate meet these requirements.

### **Toluene, xylene and dibutyl phthalate are deleterious substances.**

Toluene, xylene and dibutyl phthalate are deleterious substances that render any cosmetic that contains them injurious to children, as detailed below. Therefore, any cosmetic product that contains xylene, toluene, or dibutyl phthalate as an ingredient at any level in nail polish marketed for children should be deemed to be adulterated under section 601(a) of the Federal Food, Drug, and Cosmetic Act. Toluene, xylene, and dibutyl phthalate have been linked to a range of health effects, as detailed below.

#### *Toluene*

According to the Agency for Toxic Substances and Disease Registry (ATSDR) of the Centers for Disease Control,<sup>5</sup> exposure to toluene affects the nervous system. Exposure to low to moderate levels of toluene can cause tiredness, confusion, weakness, drunken-type actions, memory loss, nausea, loss of appetite, and hearing and color vision loss. Inhaling high levels of toluene in a short time can make you feel light-headed, dizzy, or sleepy. It also can cause unconsciousness and even death. Toluene also is a recognized developmental toxicant.<sup>6</sup> Human studies have reported developmental effects, such as central nervous system dysfunction, attention deficits, and minor craniofacial and limb anomalies, in the children of pregnant women exposed to toluene by inhalation. Other studies have linked women's exposure to toluene and an increased incidence of spontaneous abortions.<sup>7</sup>

#### *Xylene*

According to ATSDR, xylene affects the brain. Short-term exposure to high levels of xylene can cause irritation of the skin, eyes, nose, and throat; difficulty in breathing; impaired function of the lungs; delayed response to a visual stimulus; impaired memory; and possible changes in the liver and kidneys. Both short- and long-term exposure to high concentrations of xylene also can affect the nervous system, causing headaches, lack of muscle coordination, dizziness, confusion, and changes in one's sense of balance.<sup>8</sup> Long-term exposure of animals to low concentrations of xylene has not been well studied, but some information suggests that long-term exposure of animals can cause harmful effects on the kidney (with oral exposure) or on the nervous system (with inhalation exposure).<sup>9</sup>

#### *Dibutyl Phthalate*

According to ATSDR, dibutyl phthalate is an odorless and colorless or faintly yellow oily liquid that does not occur in nature. Researchers have observed birth defects in animals exposed to high levels of dibutyl phthalate during development. Death, low body weights,

<sup>4</sup> Section 601 of the Federal Food, Drug and Cosmetic Act, codified at 21 USC 361.

<sup>5</sup> ATSDR, Toxicological Profile for Toluene CAS# 108-88-3, accessed October 18, 2005 at <http://www.atsdr.cdc.gov/toxprofiles/tp56.html>.

<sup>6</sup> Office of Environmental Health Hazard Assessment (OEHHA) of the California Environmental Protection Agency, Proposition 65, Proposition 65 List of Chemicals, Current as of September 30, 2005, available at [http://www.oehha.ca.gov/prop65/prop65\\_list/Newlist.html](http://www.oehha.ca.gov/prop65/prop65_list/Newlist.html).

<sup>7</sup> U.S. EPA, Technology Transfer Network, Air Toxics Website, Hazard Summary for Toluene, accessed October 18, 2005 at <http://www.epa.gov/ttn/atw/hlthef/toluene.html>.

<sup>8</sup> ATSDR, Public Health Statement for Xylene, <http://www.atsdr.cdc.gov/toxprofiles/phs71.html>, accessed November 1, 2005.

<sup>9</sup> ATSDR, Public Health Statement for Xylene, <http://www.atsdr.cdc.gov/toxprofiles/phs71.html>, accessed November 1, 2005.

skeletal deformities, cleft palate, and damage to the testes have been observed in the offspring of animals ingesting large amounts of dibutyl phthalate.<sup>10</sup> In September 2004, the European Union banned dibutyl phthalate (DBP) and two other phthalates it classified as reproductive toxicants in all toys and childcare articles.<sup>11</sup>

The Consumer Product Safety Commission (CPSC), which does not have jurisdiction over children's cosmetics, has gone on record advising manufacturers to stop using xylene, toluene and other hazardous chemicals in children's products. Specifically, CPSC issued a guidance to manufacturers, retailers, and distributors about children's products containing liquid chemicals. This guidance states that in order to "reduce the risk of exposure to hazardous chemicals, such as mercury, ethylene glycol, diethylene glycol, methanol, methylene chloride, petroleum distillates, toluene, xylene, and related chemicals, the Commission requests manufacturers to eliminate the use of such chemicals in children's products."<sup>12</sup>

**"Customary or usual" conditions could expose children to toxic chemicals.**

According to FDA, "[m]any nail products contain poisonous substances...but are allowed on the market because they are not harmful when used as directed. They're poisonous only when ingested, which is not their intended use."<sup>13</sup> Manufacturers, however, should expect and anticipate that children may ingest nail polish under "customary or usual" conditions. Young children like to put their hands in their mouths and do so more often than older children and adults. Nail polish applied to fingernails, which may chip or peel off, offers a direct route of exposure to the chemicals contained therein. Children could face additional exposure by inhaling vapors from the nail polish when applying the product under normal conditions. Children may be more sensitive to acute inhalation exposure than adults because their narrower airways would be more sensitive to swelling effects.<sup>14</sup>

There is no "safe dose" of these chemicals for children, whose developing minds and bodies may be more vulnerable to the health effects of toxic chemical exposure. A growing body of evidence shows health effects at low doses, and chronic, multi-source exposure means that even a small amount of exposure from a variety of sources may add up to a major concern.

In the past, FDA has taken action to prohibit or restrict the use of several ingredients in cosmetic products, including bithionol, mercury, vinyl chloride, chloroform, and methylene chloride.<sup>15</sup> We are asking FDA to take similar regulatory action to remove xylene, toluene, and dibutyl phthalate from nail polish marketed for children.

## **ENVIRONMENTAL IMPACT**

This petition could only have a positive environmental impact. By removing xylene, toluene, and dibutyl phthalate from children's nail polish, FDA would be reducing the manufacture and use of three toxic chemicals in consumer products. These chemicals often find their way into our

<sup>10</sup> ATSDR, Public Health Statement for Di-n-butyl Phthalate, <http://www.atsdr.cdc.gov/toxprofiles/phs135.html>, accessed November 1, 2005.

<sup>11</sup> "Results of Competitiveness Council, Brussels, 24<sup>th</sup> September 2004," Memo/04/225.

<sup>12</sup> 16 CFR 1500.231.

<sup>13</sup> Paula Kurtzweil, "Fingernails: Looking Good While Playing Safe," *FDA Consumer*, Volume 29, Number 10, December 1995. Accessed November 14, 2005 at [http://www.fda.gov/fdac/features/095\\_nail.html](http://www.fda.gov/fdac/features/095_nail.html).

<sup>14</sup> ATSDR, Public Health Statement for Xylene, <http://www.atsdr.cdc.gov/toxprofiles/phs71.html>, accessed November 1, 2005.

<sup>15</sup> See 21 CFR 700.11, 21 CFR 700.13, 21 CFR 700.14, 21 CFR 700.18, and 21 CFR 700.19.

air, land, and water. Xylene, for example, has been found in more than 800 National Priority List toxic waste sites;<sup>16</sup> toluene has been found at more than 900 sites.<sup>17</sup>

#### **CERTIFICATION**

The undersigned certify that, to the best of our knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner that are unfavorable to the petition.

Please contact us at your earliest convenience at (202) 546-9707 to notify us of your plans to address this matter. We look forward to working with you and your staff.

Sincerely,

Edmund Mierzwinski  
Consumer Program Director  
U.S. Public Interest Research Group  
[edm@pirg.org](mailto:edm@pirg.org)

Meghan Purvis  
Environmental Health Advocate  
U.S. Public Interest Research Group  
[mpurvis@pirg.org](mailto:mpurvis@pirg.org)

Alison Cassady  
Research Director  
U.S. Public Interest Research Group  
[acassady@pirg.org](mailto:acassady@pirg.org)

#### **Cc:**

Dr. Linda Katz, Director, Office of Cosmetics and Colors, U.S. FDA  
Catherine J. Bailey, Acting Director, Division of Cosmetics and Compliance, U.S. FDA  
The Honorable Hal Stratton, Chairman, CPSC  
CPSC Commissioners Thomas Moore and Nancy Nord  
Marc Schoern, Director, Director, Recalls and Compliance Division, CPSC

#### **Attachment:**

List of children's cosmetic sets containing xylene, toluene, or dibutyl phthalate

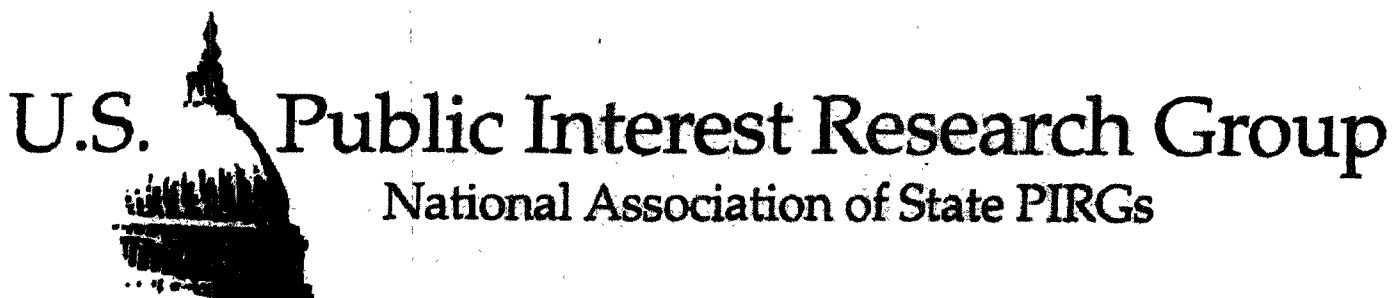
<sup>16</sup> ATSDR, ToxFAQs™ for Xylene, CAS#1330-20-7, accessed December 6, 2005 at <http://www.atsdr.cdc.gov/tfacts71.html>.

<sup>17</sup> ATSDR, ToxFAQs™ for Toluene, CAS#108-88-3, accessed December 6, 2005 at <http://www.atsdr.cdc.gov/tfacts56.html>.

**Attachment. Examples of Children's Nail Polish on Store Shelves that Contain Xylene, Toluene, or Dibutyl Phthalate**

This list is not intended to be comprehensive.

Toy Name	Where Purchased	Item Number	Brand/Manufacturer	Notes
Claire's Nail Polish	Claire's	75245-1	CBI Distributing Corp.	Nail polish contains xylene.
Claire's Nail Polish	Claire's	43229-4	CBI Distributing Corp.	Nail polish contains dibutyl phthalate.
Expressions Makeup 5 Piece Nail Polish Set	Party City	UPC: 467333	Almar Sales	Nail polish contains xylene.
Manicure Set	Dollar Tree	838713	Greenbrier International	Nail polish contains dibutyl phthalate.
Disney Cuties Tipz 'Ta Toez Polish Set	Target	89444	Added Extras LLC	Nail polish contains toluene.
Limited Too Disco Time Makeup Kit	Limited Too	55034076	Too Brands, Inc.	Nail polish contains xylene.
Disney Princess Lip Pot & Mini Nail Collection	Claire's	12459-4	boom! LLC/Disney	Nail polish contains xylene.



# Fax Coversheet

To: LYLE JAFFE

Of: FDA

Fax #: (301) 827-6870

From: ALISON CASSADY, U.S. PIRG

Total pages including this coversheet: 6

Comments: As requested, here is a revised  
version of our petition regarding toxic  
chemicals in children's nail polish.  
Thanks.

# U.S. Public Interest Research Group

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National Association of State PIRGs



November 21, 2005

## Board of Directors

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Dr. Andrew von Eschenbach  
Acting Commissioner  
U.S. Food and Drug Administration  
5600 Fishers Lane, RM1471  
Rockville MD 20857

Dear Dr. von Eschenbach:

We are writing to ask the Food and Drug Administration (FDA) to use its authority under the Federal Food, Drug and Cosmetic Act to require manufacturers to stop using xylene, toluene, and dibutyl phthalate in nail polish marketed for children under the age of 14.

In the course of doing research for its 20<sup>th</sup> annual toy safety survey, the U.S. Public Interest Research Group<sup>1</sup> (U.S. PIRG) found several examples of play cosmetic sets marketed for children with nail polish containing toxic chemicals, such as toluene, xylene and dibutyl phthalate.<sup>2</sup> In some cases, the product packaging displayed Disney characters to attract the youngest consumers; other products containing these chemicals were found in stores such as Limited Too and Claire's, which target the so-called "tween" consumers under the age of 14. Please see the attached list of products containing toluene, xylene and dibutyl phthalate that we found on store shelves.

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### **Toluene, xylene and dibutyl phthalate are deleterious substances.**

Toluene, xylene and dibutyl phthalate are deleterious substances that render any cosmetic that contains them injurious to children, as detailed below. Therefore, any cosmetic product that contains xylene, toluene, or dibutyl phthalate as an ingredient at any level in nail polish marketed for children should be deemed to be adulterated under

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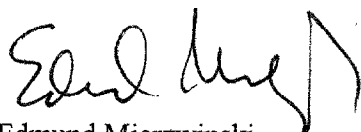
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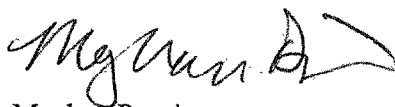
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Sincerely,



Edmund Mierzwinski  
Consumer Program Director  
U.S. Public Interest Research Group  
[edm@pirg.org](mailto:edm@pirg.org)



Meghan Purvis  
Environmental Health Advocate  
U.S. Public Interest Research Group  
[mpurvis@pirg.org](mailto:mpurvis@pirg.org)



Alison Cassady  
Research Director  
U.S. Public Interest Research Group  
[acassady@pirg.org](mailto:acassady@pirg.org)

**Cc:**

Dr. Linda Katz, Director, Office of Cosmetics and Colors, U.S. FDA  
Catherine J. Bailey, Acting Director, Division of Cosmetics and Compliance, U.S. FDA  
The Honorable Hal Stratton, Chairman, CPSC  
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Disney Cuties Tipz 'Ta Toez Polish Set	Target	89444	Added Extras LLC	Nail polish contains toluene.
Limited Too Disco Time Makeup Kit	Limited Too	55034076	Too Brands, Inc.	Nail polish contains xylene.
Disney Princess Lip Pot & Mini Nail Collection	Claire's	12459-4	boom! LLC/Disney	Nail polish contains xylene.